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Letter Ruling 11-5: Sales/Use Tax on Pharmaceutical Compounds used in Clinical Trials

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May 3, 2011

You have requested a letter ruling on behalf of ***** (hereinafter "the Company") regarding the application of the Massachusetts sales and use tax under G.L. chapters 64H and 64I to pharmaceutical products temporarily located in Massachusetts pending shipment outside the Commonwealth for use in clinical trials conducted outside the Commonwealth. The following is your representation of the facts upon which we base this ruling.

I. FACTS

The Company manufactures pharmaceutical compounds. It purchases raw inputs to be used in its pharmaceutical compounds from a vendor in California. The California vendor performs synthesis on the raw inputs and the result is the creation of pharmaceutical compounds. The Company pays a service fee to the California vendor for the synthesizing services. Title to and possession of the synthesized materials is transferred from the vendor to the Company in California at the time of shipment. The California vendor that manufactures the pharmaceutical compounds and sells them to the Company is not a Massachusetts registered vendor and therefore the Company has not provided that vendor with exemption or resale certificates in connection with those transactions. The pharmaceutical compounds are shipped to various storage facilities in the U.S., none of which are in Massachusetts. The pharmaceutical compounds are only temporarily stored in these storage facilities. The storage facilities are paid a service fee for their storage services. At this point, the pharmaceutical compounds are in their final manufactured state and could be used as a drug. The final step in the process is to place the pharmaceutical compound in a vial or syringe so it can be administered to a patient.

From the temporary storage facilities outside Massachusetts, the pharmaceutical compounds are shipped to fill/finish manufacturers located in various states, including Massachusetts. Here vials and syringes are filled with the pharmaceutical compounds. The fill/finish processors are paid a service fee for their services. Once the pharmaceutical compounds are placed in vials and syringes, they are shipped back to the temporary storage facilities. The vials and syringes are then shipped to clinical trial locations and the pharmaceutical compounds are administered to patients during clinical trials, which thus far have taken place in Ohio. The clinical trials are supervised by parties that are unrelated to the Company. These parties are paid a service fee for administering the clinical trials. The trials are administered to qualifying patients who suffer from diabetes. The trials and the patients are under the supervision of licensed physicians. While a regular prescription for the drug is not issued because the drug has only been approved by the FDA for clinical trial usage, the

supervising licensed physicians follow strict clinical trial protocols that specify doses for each patient.

In addition, some pharmaceutical compounds are shipped from the storage facilities to research and development locations within the United States for further lab, stability and toxicology testing. The labs providing this service to the Company are unrelated and are paid a service fee for the research and development services. The amount of the pharmaceutical compounds shipped to research locations is small compared to the number used in clinical trials. These research and development vendors are located throughout the United States, excluding Massachusetts.

The Company owns the pharmaceutical compounds until they are administered to patients during the clinical trials. However, all of the activities described above are outsourced by the Company to independent providers or vendors.

II. RULING

For the reasons discussed below, we rule that the pharmaceutical products at issue, which are temporarily located in Massachusetts pending shipment outside of the Commonwealth, are not subject to the Massachusetts sales and use tax.

III. DISCUSSION

Massachusetts imposes a 6.25 percent sales tax on sales and rentals of tangible personal property in Massachusetts by any vendor, unless otherwise exempt. See G.L. c. 64H, § 2. The Massachusetts use tax, codified under G.L. c. 64I, § 2, imposes “an excise . . . upon the storage, use or other consumption in the commonwealth of tangible personal property purchased from any vendor for storage, use or consumption within the commonwealth. A statutory “use” is defined to mean and include (i) the exercise of any right or power over tangible personal property incident to the ownership of that property” G.L. c. 64I, § 1.

The acts constituting the exercise of rights and powers over property must occur within the Commonwealth in order to make out a taxable “use.” *J.C. Penney Co., Inc. v. Commissioner of Revenue*, A.T.B. Docket No. F239834 (January 29, 1999), reversed on other grounds, *Commissioner of Revenue v. J.C. Penney*, 431 Mass. 684 (2000); See also Letter Ruling 01-3. However, “[t]he terms “store” and “storage,” and “use” shall not include the keeping, retaining or exercising of any right or power over tangible personal property for the purpose of subsequently transporting it outside of the commonwealth for use thereafter solely outside of the commonwealth, or for the purpose of being processed, fabricated or manufactured into other tangible personal property to be transported outside of the commonwealth and thereafter used solely outside the commonwealth.” G.L. c. 64I, § 1.

It is your position that the process of fulfilling the fill/finish services, which results in the temporary storage of the Company’s pharmaceutical compounds in Massachusetts, and which also results in an exercise of a right or power incident to ownership of tangible personal property in Massachusetts, is exempt from the sales and use tax.^[1] In addition, you assert that the pharmaceutical compounds meet the definition of “medicine” under Massachusetts law. In support of this position, you state that these pharmaceutical compounds have been approved by the United States FDA for use in clinical trials. You also assert that use of these pharmaceutical compounds in clinical trials qualifies as “on prescription of registered physicians.”

Under the facts you have presented, we rule that although a portion of the fill/finish process takes place in Massachusetts, such temporary storage of property subsequently transported outside the Commonwealth for use outside the Commonwealth is not a use subject to tax pursuant to G.L. c. 64I, §§ 1,2. Having so concluded, we do not need to address the issue of whether these pharmaceutical compounds meet the definition of medicine in G.L. c. 64H, § 6(l).

Very truly yours,

/s/Navjeet K. Bal

Navjeet K. Bal
Commissioner of Revenue

NKB:MTF:wm

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[\[1\]](#) Although the Company outsources processing activities to third parties, we note this is irrelevant to the sales/use tax issue because the Company is the owner of the tangible personal property until it is actually administered to patients. Under those circumstances, the use tax exemption also applies when the property is in the hands of the third party.